UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SEB INVESTMENT MANAGEMENT AB, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

ENDO INTERNATIONAL PLC; ENDO HEALTH SOLUTIONS INC.; PAUL V. CAMPANELLI; BLAINE T. DAVIS; MATTHEW W. DAVIS; RAJIV KANISHKA LIYANAARCHCHIE DE SILVA; IVAN GERGEL; SUSAN HALL; DAVID P. HOLVECK; ALAN G. LEVIN; JULIE H. MCHUGH; SUKETU P. UPADHYAY; DANIEL A. RUDIO; ROGER H. KIMMEL; SHANE M. COOKE; JOHN J. DELUCCA; ARTHUR J. HIGGINS; NANCY J. HUTSON; MICHAEL HYATT; WILLIAM P. MONTAGUE; JILL D. SMITH; and WILLIAM F. SPENGLER,

Defendants.

Civ. A. No. 2:17-CV-3711-TJS

ORAL ARGUMENT REQUESTED

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

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Defendants submit this memorandum of law in support of their Motion to Dismiss the Amended Complaint (cited as "¶ _").

Preliminary Statement

This case is about Endo's efforts to develop a crush-resistant version of an opioid painkilling medication called "Opana ER." The FDA approved original Opana ER in 2006 and approved a reformulated version, intended to be less susceptible to misuse and abuse by crushing and snorting, in 2011. From 2012 into 2017, Endo repeatedly sought the FDA's permission to market and label reformulated Opana ER as having "abuse deterrent" qualities. During that time, Endo and some of its executives made statements expressing optimism about reformulated Opana and the possibility that the FDA would eventually approve Endo's marketing and labeling requests.

Ultimately, the FDA not only rejected Endo's requests but also, in June 2017, after concerns about the national opioid-abuse crisis had grown, requested that Endo voluntarily withdraw reformulated Opana ER from the market. The FDA acknowledged that "[t]his is the first time" the FDA had ever made such a request of any company "due to the public health consequences of abuse" of a medication. (¶ 149.) It explained that, "[w]e are facing an opioid epidemic" and that "[n]ow, with more information about the . . . product," it was "concern[ed] that the benefits of the drug [Opana ER] may no longer outweigh its risks." (*Id.*) In this lawsuit, Plaintiff—with the benefit of hindsight, but no contemporaneous facts—contends that Endo's earlier optimistic statements were false. It asserts claims under Section 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Sections 11 and 15 of the Securities Act of 1933 ("Securities Act") against 22 defendants. These claims fail as a matter of law for three independent reasons:

1. Plaintiff Cannot Assert Securities Act Claims In This Court. The Securities Act claims should be dismissed because the same claims—by the same plaintiff class against the same defendants based on the same securities offering—are already proceeding in an earlier-filed class action in the Chester County Court of Common Pleas. This "claim splitting" of the class's Securities Act claims is barred by the doctrine of *Colorado River* abstention, which seeks to avoid wasting judicial and party resources with such duplicative litigation.

2. The Amended Complaint Does Not Establish Any False Statements. All of the claims should be dismissed for failure to allege a false statement. Despite its 125-page length, the Amended Complaint does not include a single internal document, confidential witness or other fact to support the notion that Endo and its representatives did not legitimately believe the truth of each and every positive statement made. On the contrary, its sheer bulk—along with its pleading technique of piling cross-references on top of other cross-references—renders it the sort of "puzzle pleading" that courts routinely reject, precisely because it is impossible to tell just what is being said about why the statements were supposedly false. In any case, to the extent the Amended Complaint can be deciphered, it purports to engage in impermissible "hindsight pleading" and alleges no facts establishing that any statements were false at the time they were made. Moreover, many statements identified are protected as opinions, general corporate optimism (or "puffery") or forward-looking statements. Further, there is no fact establishing that any statement by any of the individual defendants was false.

3. The Amended Complaint Does Not Establish Scienter. The Exchange Act claims should be dismissed because the Amended Complaint does not come close to establishing the required "strong inference" of scienter, or fraudulent intent. It does not allege a single fact showing that *any* defendant knew of any fact that rendered their statements untrue or that they

knew that the FDA would later reject their labeling requests. That Plaintiff has named as defendants nine individuals—many of whom are alleged to have made only *one* misstatement in a five-year period—without any factual basis is fundamentally improper. There is simply no basis on which any inference of fraud can be drawn as to any defendant. Indeed, the far more compelling inference is that Endo advocated for Opana ER with the FDA for five years and the FDA ultimately came to a different conclusion with additional data and a new focus on the "opioid epidemic."

The Amended Complaint lacks anything approaching the particularized factual allegations necessary to state a claim. It should be dismissed.

Background

A. Procedural Background

1. The *MissPERS* Case

This case is one of four U.S. securities litigations involving Endo. One of the other cases, *Public Employees' Retirement System of Mississippi v. Endo*, No. 17-02081-MJ ("*MissPERS*"), was filed in the Court of Common Pleas of Chester County, Pennsylvania, on February 28, 2017. (Ex. 1.) That case asserts claims seeking damages under Sections 11, 12(a)(2) and 15 of the Securities Act based on Endo's June 2015 secondary securities offering on behalf of "all persons or entities that purchased or otherwise acquired Endo common stock pursuant or traceable to the Company's [June 2, 2015] Registration Statement" against Endo, the officers and directors who signed the registration statement for that securities offering, and the underwriters of that offering.

(Ex. 1, at ¶ 1.)[1] *MissPERS* primarily alleges that the registration statement misrepresented the effects on Endo's sales of hydrocodone products after the FDA made it more difficult for doctors to prescribe them. (Ex. 1.) On October 16, 2017, the plaintiff in *MissPERS* filed an amended complaint, which continues to assert a Securities Act claim on behalf of the same plaintiff class, against the same defendants, and based on the same Registration Statement at issue here. (Ex. 2.) On December 8, 2017, defendants filed preliminary objections arguing that the amended complaint fails to state a claim.[2] Those objections are fully briefed and pending before the Chester County court.[3]

2. This Case

This case was filed on August 18, 2017. (Dkt No. 1.) The original complaint sought to assert claims under "under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934." (*Id*. at 2.) Several lead plaintiff candidates, including Plaintiff, moved for appointment, pursuant

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[1] "To resolve a 12(b)(6) motion, a court may properly look at public records, including judicial proceedings, in addition to the allegations in the complaint." *S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999).

[2] The *MissPERS* case was stayed (other than the briefing on defendants' preliminary objections) while the U.S. Supreme Court decided *Cyan, Inc. v. Beaver Cty. Employees Retirement Fund* (No. 15-1439), which considered the question of whether state courts maintained concurrent jurisdiction over Securities Act class actions. On March 20, 2018, the Supreme Court decided *Cyan* and held that state courts do have such jurisdiction. *See Cyan, Inc. v. Beaver Cty. Employees Ret. Fund*, No. 15-1439, 2018 WL 1384564 (Mar. 20, 2018). Accordingly, the *MissPERS* case is proceeding in the Chester County court.

[3] The two other Endo securities cases are *Friedman v. Endo International plc*, No. 1:16-cv-03912-JMF (S.D.N.Y.), and *Pelletier v. Endo International plc*, No. 17-cv-05114-TJS (E.D. Pa.). Neither is relevant to this motion. In *Friedman*, on January 16, 2018, that court granted defendants' motion to dismiss with prejudice, *Friedman v. Endo Int'l PLC*, No. 16-CV-3912 (JMF), 2018 WL 446189, at *1 (S.D.N.Y. Jan. 16, 2018), and plaintiffs have filed a motion to alter that judgment to file another amended complaint. In *Pelletier*, this Court currently has before it motions for the appointment of lead plaintiff and lead counsel. A fifth securities litigation has also been filed against Endo in Canada in the Ontario Superior Court of Justice, *Makris v. Endo International plc*, [2017] No. 17-cv-573962 (ONSC).

to Section 21D(a)(3) of the Exchange Act, 15 U.S.C. § 78u-4(a)(3)(B). (*See* Dkt. No. 11.) No lead plaintiff candidate expressed an intention to bring Securities Act claims. On December 4, 2017, Plaintiff was appointed "lead plaintiff." (Dkt. No. 29.) On February 5, 2018, Plaintiff filed its Amended Complaint, which for the first time added claims under Sections 11 and 15 of the Securities Act based on the same June 2015 secondary offering as the *MissPERS* case, on behalf of the same plaintiff class against the same individual defendants. (*See* ¶¶ 352-65.)

B. Factual Background[4]

1. Endo

Certain of Endo's operating subsidiaries manufacture generic and branded pharmaceuticals, including various pain management products. (¶¶ 25, 38.) Endo Health Solutions Inc. is subsidiary of Endo. (¶ 26.)

2. The Individual Defendants

a. The Exchange Act Individual Defendants

The Amended Complaint names nine current and former Endo officers as defendants for its Exchange Act claims (the "Exchange Act Individual Defendants"). None was employed by Endo during the entire class period and most are alleged to have made only one or two statements during that period:

- Paul Campanelli: CEO and board member since September 23, 2016 (¶ 27);
- Blaine Davis: former Senior Vice President and General Manager of Specialty Pharmaceuticals, beginning in January 2015; previously Senior Vice President of Corporate Affairs (¶ 28);
- Matthew Davis: Senior Vice President, Research and Development Branded Pharmaceuticals since January 3, 2017 (¶ 29);

[4] Plaintiffs' allegations are accepted as true only for the purposes of this motion.

- Rajiv Kanishka Liyanaarchchie De Silva: former President and CEO, and a member of Endo's board from March 18, 2013 to September 22, 2016 (¶ 30);
- Ivan Gergel: former Executive Vice President, Research and Development from April 11, 2008 to March 31, 2014, and Chief Scientific Officer from 2011 to March 31, 2014 (¶ 31);
- Susan Hall: former Executive Vice President and Chief Scientific Officer from March 10, 2014 to December 2016 (¶ 32);
- David P. Holveck: former President and CEO and board member from April 1, 2008 to December 12, 2012 (¶ 33);
- Alan G. Levin: former CFO from June 1, 2009 to fall 2013 (¶ 34); and
- Julie H. McHugh: former COO from March 2010 to May 29, 2013 (¶ 35).

The Section 10(b) and 20(a) claims are brought against Endo, Endo Health Solutions and the Exchange Act Individual Defendants. (¶¶ 25-36.)

b. The Securities Act Individual Defendants

The Amended Complaint also asserts claims under the Securities Act against certain current and former Endo board members and officers (the "Securities Act Individual Defendants") who signed the registration statement for Endo's June 2015 secondary securities offering. (¶¶ 354-64.) These individuals are: Mr. De Silva (¶ 365); Suketu P. Upadhyay, Endo's former CFO and Executive Vice President (¶ 354); Daniel A. Rudio, Endo's Chief Accounting Officer and Controller (¶ 355); current board members Roger H. Kimmel, Shane M. Cooke, Nancy J. Hutson, Michael Hyatt, William P. Montague, and Jill D. Smith (¶¶ 356-57, 360-63); and former board members John J. Delucca, Arthur J. Higgins, and William F. Spengler (¶¶ 358-59, 364).

The Section 11 and 15 claims are brought against Endo and the Securities Act Individual Defendants. (¶ 365.)

3. The FDA Approves Original Opana ER In 2006

In 2006, following FDA approval, Endo introduced Opana ER. (¶ 55.) Opana ER is an extended-release pill form of a century-old opioid intended to provide long-lasting pain relief. (¶ 50.) Opana ER, like other opioids, had addictive qualities and was susceptible to abuse. (¶ 52.) The most common form of abuse was intranasal, by crushing and snorting it. (¶ 54.)

4. The FDA Approves Reformulated Opana ER In 2011

In an attempt to address the risk of abuse by crushing and snorting, Endo developed a reformulated version of Opana ER intended to be "crush-resistant." (¶ 63.) In July 2010, Endo submitted to the FDA a new drug application seeking approval for reformulated Opana ER. (¶ 66.) Plaintiff alleges that, as part of this application, Endo submitted several studies to the FDA: "Study 108," described as an "*in vivo* bioavailability study" (¶ 68), "Study 109," described as an "*in vivo* human abuse potential and drug-liking study" (¶ 69), "Study 901," described as assessing human manipulation of opioid products (¶ 71), and "Study 902," described as testing the manipulation of reformulated Opana ER "for intranasal administration" (¶ 72). Plaintiff does not attach these studies to the Amended Complaint. Nor does it quote or allege any facts about the studies' methodologies, authors, participants, limitations, or data.

On December 9, 2011, the FDA approved reformulated Opana ER, finding it "safe and effective for the management of severe pain." (¶ 78.) The FDA denied Endo's request to label the new product as having "abuse deterrent properties" because the data was inadequate at that time. (*Id.*) Endo began selling reformulated Opana ER in February 2012. (¶ 80.)

5. Endo Seeks FDA Approval For Abuse-Deterrent Labeling In 2012

Endo continued to seek FDA approval to label reformulated Opana ER as abuse-deterrent and to seek an FDA finding that original Opana ER had been discontinued for safety reasons.

(¶¶ 84-95.) In November 2012 and March 2013, Endo supplemented its FDA submissions with data collected by the National Addictions Vigilance Intervention and Prevention Program ("NAVIPPRO") and the Researched Abuse Diversion and Addiction-Related Surveillance System ("RADARS")—both independent organizations. (¶¶ 88, 99-100.) Although the Amended Complaint excerpts charts that purport to have been created from data collected from these systems, as well as from another database, the FDA's Adverse Event Report System ("FAERS"), those charts are dated *years later*—in 2016 and 2017. (¶¶ 123-31.)

On May 10, 2013, the FDA denied Endo's requests. (¶ 109.) Although the FDA again acknowledged reformulated Opana ER's "increased ability . . . to resist crushing," it found the data "preliminary" and "inconclusive" and also found some evidence of intravenous abuse. (¶¶ 110-11.)

6. Endo Again Seeks FDA Approval For Abuse-Deterrent Labeling In 2015 And 2016

In May 2015, Endo continued its dialog with the FDA regarding labeling the abuse-deterrent properties of reformulated Opana ER. (¶¶ 128, 133.) For example, Mr. De Silva, Endo's former CEO, explained that "in our view, we have sufficient and robust enough data for their decision." (¶ 226). After a meeting with the FDA in June 2015, Mr. De Silva stated that "we left that meeting with more optimism than before" and that Endo intended to seek approval again, "likely . . . the back end of this year or early in 2016." (¶ 232.)

In January 2016, Endo resubmitted its request to the FDA. (¶ 133.) In August 2016, Endo withdrew the request because the FDA "was concerned that some of these data suggested that reformulated Opana ER may be less safe than original Opana ER." (¶¶ 135-136.)

7. The FDA Seeks Reformulated Opana ER's Voluntary Withdrawal From The Market In June 2017

By 2017, concerns about a national "opioid crisis" had reached a crescendo. (¶¶ 46-49.) In January 2017, the FDA announced that an Advisory Committee would meet to review data and alleged safety concerns pertaining to reformulated Opana ER. (¶¶ 137-38.) On March 14, 2017, the Advisory Committee voted 18 to 8 that the benefits of reformulated Opana ER "did not outweigh its risks." (¶ 146.)

On June 8, 2017, the last day of the class period, the FDA announced that, while it had previously determined reformulated Opana ER "met the regulatory requirements for approval," in light of the "opioid epidemic" and "[n]ow, with more information about the risks of the reformulated product" and out of "concern that the benefits of the drug may no longer outweigh its risks," the FDA "[wa]s taking steps to remove the reformulated Opana ER from the market." (¶ 149.) In its press release, the FDA acknowledged that this decision was unprecedented: it marked "the first time the agency has taken steps to remove a currently marketed opioid medication from sale due to the public health consequences of abuse." (*Id.*) The agency explained that it would "continue to examine the risk-benefit profile of all approved opioid analgesic products"—not just Opana ER or other Endo medications—"and take further actions as appropriate as part of [its] response to this public crisis.[5] Endo withdrew Opana ER from the market. (¶ 151.) Its stock price declined. (¶ 150.) This lawsuit followed.

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[5] *See* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm, also attached as Exhibit 3. Because the FDA press release is excerpted in the Amended Complaint and is integral to Plaintiff's claims (*see, e.g.*, ¶¶ 149, 287-289), the Court may consider the full press release here. *Downs v. Andrews*, 639 F. App'x 816, 817 n.1 (3d Cir. 2016) ("document[s] integral to or explicitly relied upon in the complaint" may be considered upon a motion to dismiss) (citation omitted); *Starks v. Coloplast Corp.*, No. 13-3872, 2014 WL 617130, at *2

Argument

I. THE SECURITIES ACT CLAIMS SHOULD BE DISMISSED UNDER *COLORADO RIVER* BECAUSE THEY ARE ALREADY BEING LITIGATED IN CHESTER COUNTY COURT

This Court should dismiss the Securities Act claims pursuant to *Colorado River Water Cons. Dist. v. United States*, 424 U.S. 800 (1976), because those claims have already been asserted by the same plaintiff class in state court.[6] The *Colorado River* doctrine permits federal courts to decline jurisdiction where a parallel action is already proceeding in state court. *See Moses H. Cone Memorial Hospital v. Mercury Construction Corp*., 460 U.S. 1, 14-15 (1983). It "rest[s] on considerations of 'wise judicial administration, giving regard to conservation of judicial resources and comprehensive disposition of litigation.'" *Colorado River*, 424 U.S. at 817 (citation omitted).

Colorado River involves a two-part inquiry. "The initial question is whether there is a parallel state proceeding that raises 'substantially identical claims [and] nearly identical allegations and issues.'" *Chambers v. Wells Fargo Bank, N.A*., No. 16-3162, 2018 WL 1225128, at *2 (3d Cir. Mar. 9, 2018) (citation omitted). "This does not mean that the proceedings must be identical, but rather substantially similar." *Robinson v. Ruiz*, 772 F. Supp. 212, 214 (D. Del. 1991). There is no question that this case and *MissPERS* are parallel proceedings.

(E.D. Pa. Feb. 18, 2014) ("FDA reports published on the FDA website are public records that the court may judicially notice" in ruling on a motion to dismiss).

[6] Notably, this Court did not authorize Plaintiff to bring Securities Act claims. Plaintiff never asked for that authority or indicated its intention to bring such claims, and the Order appointing Plaintiff lead plaintiff was only under Section 21D(a)(3) of the Exchange Act. (Dkt. No. 29.) The Securities Act has a separate lead plaintiff provision. *See* 15 U.S.C. § 77z-1. No plaintiff provided notice to the proposed class of any Securities Act claims, as the PSLRA requires. *See* 15 U.S.C. § 77z-1(a)(3)(A). Other courts have dismissed claims in this circumstance. *See In re Sandridge Energy, Inc. Sec. Litig.*, No. CIV-12-1341-W, 2015 WL 3652522, at *5 (W.D. Okla. May 11, 2015) (dismissing claims raised in amended complaint based on lead plaintiff's "absence of compliance with the notice provision of the PSLRA" with respect to those claims).

In both cases, the exact same plaintiff class (those who "purchased or otherwise acquired common stock . . . pursuant or traceable to Endo's June 2, 2015 offering") brings claims for damages under Section 11 and 15 of the Securities Act based on the same June 2015 securities offering and against the same group of individual defendants (as well as several financial institutions, in *MissPERS*). (¶ 1; Ex. 2, at ¶ 1.) This case and *MissPERS* seek to split the plaintiff class's theories by challenging different statements in the same June 2015 registration statement. Each case, if it proceeds beyond a motion to dismiss, would litigate identical issues involving the June 2015 securities offering process, the basis for the truthfulness of the statements in the registration statement, and potential damages resulting from any misstatements. The two cases are plainly parallel. *See Ingersoll-Rand Fin. Corp. v. Callison*, 844 F.2d 133, 138 (3d Cir. 1988) (affirming abstention under *Colorado River* where the same parties asserted similar claims); *Allied Nut & Bolt, Inc. v. NSS Indus., Inc.*, 920 F. Supp. 626, 632-33 (E.D. Pa. 1996) (dismissing in favor of parallel state action where actions "arise from the same transaction and occurrence, involve the same parties, entail consideration of the same factual and legal issues, and seek essentially the same relief").

The second part of the *Colorado River* inquiry considers six non-exclusive factors: (1) which court first assumed jurisdiction over property involved, if any; (2) the relative convenience of the fora; (3) the desirability of avoiding piecemeal litigation; (4) the order in which jurisdiction was obtained; (5) whether federal or state law applies; and (6) whether the state court will adequately protect the federal plaintiff's interests. *BIL Mgmt. Corp. v. New Jersey Econ. Dev. Auth.*, 310 F. App'x 490, 491 (3d Cir. 2008). "The factors must be balanced in 'a pragmatic, flexible manner with a view to the realities of the case at hand.'" *Id.* (quoting *Moses H. Cone*, 460 U.S. at 16). These factors unequivocally favor abstention here. The

Chester County court had jurisdiction over the Securities Act claims long before this Court, the convenience to the parties in the two courts is essentially identical, there is a strong interest in avoiding piecemeal litigation, the U.S. Supreme Court in *Cyan* just confirmed that state courts have concurrent jurisdiction over the Securities Act claims,[7] and there is no reason that the state court cannot protect the plaintiff class's interests here.

Moreover, this case typifies "[t]he predominant concern expressed in *Colorado River* and its progeny": "'the avoidance of piecemeal or purely duplicative litigation and the concomitant waste of judicial resources.'" *Mouchantaf v. Int'l Modeling & Talent Ass'n*, 368 F. Supp. 2d 303, 307 (S.D.N.Y. 2005) (citation omitted). It would be entirely duplicative, and a complete waste of judicial and party resources, to allow both cases to proceed, as it would force the same defendants to provide discovery, sit for depositions, and defend themselves against the same questions twice. The importance of avoiding such a wasteful result has been echoed by the Third Circuit, courts in this District and Pennsylvania state courts enforcing "[t]he longstanding rule against improper claim splitting [which] prohibits a plaintiff from prosecuting his case piecemeal and requires that all claims arising out of a single alleged wrong be presented in one action." *Prewitt v. Walgreens Co.*, No. CIV. A. 12-6967, 2013 WL 6284166, at *5 (E.D. Pa. Dec. 2, 2013) (preventing claim-splitting promotes "judicial economy by protecting defendants from having to defend against multiple identical, or nearly identical, lawsuits and by protecting courts from having to expend judicial resources on piecemeal litigation"); *accord Walton v. Eaton Corp.*, 563 F.2d 66, 70 (3d Cir. 1977) (a plaintiff has "no right to maintain two separate actions involving the same subject matter at the same time in the same court and against the same

[7] Although the Chester County court is applying federal (not state) law, this factor has "less significance" where, as here, "state courts possess concurrent jurisdiction." *Manna v. Greenburgh No. 11 Sch. Dist.*, 2 F. Supp. 2d 461, 469 (S.D.N.Y. 1998).

defendant"); *Hillgartner v. Port Auth. Of Allegheny Cty.*, 936 A.2d 131, 141 (Pa. Commw. 2007) ("'[A] plaintiff must recover all damages arising from given operative facts in a single action when the first forum has the ability to give the relief sought in the second forum.'") (citation omitted).[8]

This Court should bar Plaintiff from splitting the Securities Act claims here and dismiss them under *Colorado River*. *See Katz v. Gerardi*, 655 F.3d 1212, 1219 (10th Cir. 2011) (affirming dismissal of Securities Act claims under the rule against claim splitting where plaintiff "filed two cases in the same district court, involving the same subject matter, seeking the same claims for relief against the same defendants."); *Clark v. Lacy*, 376 F.3d 682, 687, 688 (7th Cir. 2004) (affirming dismissal under *Colorado River* to avoid "duplicating the amount of judicial resources" where a state court "can resolve these questions just as effectively"); *Allied Nut & Bolt*, 920 F. Supp. at 632 (dismissing claim under *Colorado River* where "wise judicial administration" counseled "against 'piecemeal litigation'") (citations omitted); *Fidelity v. Larken Motel Co.*, 764 F. Supp. 1014, 1017-19 (E.D. Pa. 1991) (dismissing claim under *Colorado River* seeking the enforcement of a contract that was subject to a claim seeking its cancellation in state court).[9]

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[8] In addition, because the *MissPERS* case involves underwriters who are not defendants in this case, "there is a risk of inconsistent outcomes not preventable by principles of *res judicata* and collateral estoppel. In other words, a decision from the [state court] could well preclude claims before this court, but the reverse is not true (because [the underwriter defendants] are not parties to the federal case)." *See General Star Intern. Indem. Ltd. v. Chase Manhattan Bank*, No. 01 CIV. 11379, 2002 WL 850012 at *7 (SDNY 2002) (staying federal action in deference to state court action).

[9] As these cases make clear, the prohibition against claim-splitting provides an independent basis for dismissal. Where the claim, as here, is split between federal and state courts, such claims are often dismissed within the *Colorado River* framework, but this Court may also dismiss the Section 11 claims as improper claim-splitting separately from its consideration of *Colorado River* abstention. *See Fernandes v. Quarry Hill Assoc. LP*, 2010 WL 5439785, at *11

II. PLAINTIFF'S SECTION 10(B) AND SECTION 11 CLAIMS SHOULD BE DISMISSED FOR FAILURE TO ALLEGE A MATERIAL FALSE OR MISLEADING STATEMENT AND SCIENTER

A. The Elements Of Plaintiff's Section 10(b) And Section 11 Claims

To state a claim under Section 10(b) of the Exchange Act, a plaintiff must allege facts establishing "(1) a material misrepresentation or omission, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation or omission, (5) economic loss, and (6) loss causation." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014). To state a claim under Section 11 of the Securities Act, a plaintiff must establish that it purchased shares in or traceable to a materially false or misleading registration statement. *See In re Constar Intern. Inc. Secs. Litig.*, No. 03-5020, 2008 WL 614551, at *2 (E.D. Pa. Mar. 4, 2008).

B. Heightened Pleading Standards Apply To Plaintiff's Claims

Under both Section 10(b) and Section 11, a plaintiff must allege "facts" establishing a "plausible" claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 679, 682 (2009). "[M]ere conclusory statements[] do not suffice." *Id.* at 678. To state a Section 10(b) claim, a plaintiff must also satisfy the heightened pleading requirements of both Rule 9(b) and the PSLRA. *See In re NutriSystem, Inc. Sec. Litig.*, 653 F. Supp. 2d 563, 577 (E.D. Pa. 2009). Rule 9(b) "requires, at a minimum, that plaintiffs support their allegations of securities fraud with all of the essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where and how' of the events at issue." *In re Rockefeller Ctr. Props., Inc. Secs. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (citation omitted). The PSLRA imposes several additional requirements, including that plaintiffs (i) "specify each statement alleged to have been

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(D. Mass. Dec. 28, 2010) (finding federal claims precluded due to claim splitting in first-filed state case).

misleading [and] the reason or reasons why the statement is misleading," and (ii) "with respect to each [alleged] act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" (*i.e.*, scienter). 15 U.S.C. § 78u-4(b)(1), (2). Complaints that fail to meet these standards must be dismissed. *See id*. § 78u-4(b)(3)(A).

Because scienter is not an element of a Section 11 claim, such claims generally are not required to meet the heightened pleading standards. *See In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 577 (E.D. Pa. 2009). However, where a Section 11 claim is "grounded in fraud," it must comply with those standards. *See Cal. Pub. Empls.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 160-63 (3d Cir. 2004). That is the case here. Amended Complaint paragraph 371, which purports to set forth the bases for the Securities Act claims, expressly incorporates the exact same allegations that purport to form the bases for Plaintiff's Section 10(b) fraud claim. (*See* ¶ 371 (citing ¶¶ 67-69, 71-73, 87-92, 98-99, 102, 109-12, 123-27, 130-31, 141-44).); *see also In re Adolor Corp.*, 616 F. Supp. 2d at 578 (Rule 9(b) applies where the "core theory of fraud permeates" a Section 11 claim) (citation omitted).

The Amended Complaint does not state a Section 10(b) or Section 11 claim.

C. Plaintiff Has Failed To Allege That Any Statement Was False Or Misleading

1. The Amended Complaint Employs Impermissible "Puzzle Pleading"

Courts in this circuit and elsewhere routinely dismiss complaints employing "puzzle pleading" tactics that fail to connect alleged misstatements to the specific facts and reasons why they are allegedly false or misleading. *See*, *e.g.*, *In re Autodesk, Inc. Sec. Litig.*, 132 F. Supp. 2d 833, 842 (N.D. Cal. 2000) ("The court is unwilling . . . to search through the 51-page [complaint] as plaintiffs' counsel suggested, and also finds that it would be unfair to compel defendants to do so. . . . '[a] complaint is not a puzzle' . . . .") (citation omitted). It is well-established that a court

should not have to "jump[] from page to page . . . to link the alleged misstatements to the background that supposedly makes them false and misleading." *Lord Abbett Aff. Fund, Inc. v. Navient Corp.*, Civ. No. 16-112-GMS, 2017 WL 3891676, at *3 (D. Del. Sept. 6, 2017) (quoting *Conlee v. WMS Indus., Inc.*, 2012 WL 3042498, at *4 (N.D. Ill. July 25, 2012)). Nor should a court "have to play connect-the-dots in order to identify the facts and trends upon which plaintiffs base their claim." *In re Dura Pharms., Inc. Sec. Litig.*, No. 99CV0151–L(NLLS), 2000 WL 33176043, at *6 (S.D. Cal. July 11, 2000) (citation omitted). That is precisely what the Amended Complaint requires in this case.

The Amended Complaint consists of 125 pages and 394 paragraphs. In an attempt to plead a Section 10(b) claim, it devotes over 40 pages to a "Summary of Defendants' Fraud." (¶¶ 37-151.) Its next 30-plus pages purport to challenge as false dozens of statements from 2012 through 2017. (¶¶ 152-263.) Those pages, however, do not identify facts establishing why those statements were false. Instead, the Amended Complaint refers repeatedly to paragraphs 160 and 203. Plaintiffs then contend that the statements in 14 paragraphs (¶¶ 162, 165, 167, 169, 175, 176, 178, 180, 184, 188, 193, 194, 201 and 202) are all false "for the reasons alleged above in ¶ 160," or as "alleged above at ¶ 160." Plaintiff also contends that the statements in 24 other paragraphs (¶¶ 205, 207, 208, 212, 213, 215, 217, 220, 221, 223, 228, 229, 234, 235, 238, 239, 243, 244, 247, 248, 251, 252, 259 and 263) are all false "for the reasons alleged above in [or at] ¶ 160 and ¶ 203," or as "alleged above at ¶¶ 160 and 203."

Paragraphs 160 and 203, however, also do not allege any facts. Instead, they cross-reference still other paragraphs, elsewhere in the complaint. Paragraph 160 cross-references paragraphs 67-69, 71-73, 87-92, 98-99, 102 and 109-12 (*see* ¶ 160), and paragraph 203 cross-references paragraphs 123-27, 130-31 and 141-44 (*see* ¶ 203). The Securities Act allegations do

more of the same: paragraph 371 purports to allege false statements in Endo's "2014 Form 10-K and 1Q15 Form 10-Q incorporated by reference into" the June 2015 registration statement by cross-referencing allegations in paragraphs 67-69, 71-73, 87-92, 98-99, 102, 109-12, 123-27, 130-31 and 141-44. (*See* ¶ 371.)

This is puzzle-pleading at its worst. It is precisely the sort of "connect-the-dots" approach that has been roundly rejected. As the *Lord Abbett* court recently explained, a complaint that "frequently cross-references other paragraphs" and "mak[es] it very difficult to follow" should be dismissed. 2017 WL 3891676, at *3 (dismissing claims); *see also In re Wilmington Trust Sec. Litig.*, 852 F. Supp. 2d 477, 490 (D. Del. 2012) (dismissing claims where "plaintiffs have not specifically identified the reason or reasons why each statement is false or misleading" and instead cite "to a laundry list of reasons why a statement could be untrue").[10] The Amended Complaint should be dismissed for the same reasons.

2. The Amended Complaint's Hindsight Allegations Fail To Establish A False Or Misleading Statement

The Amended Complaint attempts to challenge Endo's positive statements about reformulated Opana ER and its prospects for abuse-deterrent labeling. This is a difficult task under any circumstances, as companies are not "required to take a gloomy, fearful or defeatist

[10] *See also Wilmington Trust*, 852 F. Supp. 2d at 490 ("Most often the complaint contains two or three quoted words or a short quoted phrase without providing the context of the full sentence; alternatively, longer quotes are provided with several ellipses. . . . In short, the alleged misstatements are provided without sufficient context, and the complaint fails to identify the specific statements on which plaintiffs base each of their claims."); *In re NTL Inc. Sec. Litig.*, No. 02 Civ. 3013 (LAK), 2003 WL 21767948, at *1 (S.D.N.Y. July 31, 2003) ("While [the 62-page amended complaint] contains a superabundance of detail and lengthy summaries of various alleged press releases and other public statements by defendants, it is far from clear which of these pronouncements are said to have been false or misleading, which parts of them are said to have been so, and exactly why plaintiffs claim they are is [sic] so. . . . Thus, the Court is left to guess . . . .").

view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business they manage." *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 603 n.36 (S.D.N.Y. 2016) (citation omitted); *see also Winer Family Tr. v. Queen*, Civ. No. 03-4318, 2005 WL 102936, at *8 (E.D. Pa. Jan. 13, 2005) (noting that "premature optimism" is inactionable), *aff'd*, 503 F.3d 319 (3d Cir. 2007). In this case, Plaintiff does not come close to establishing that any of these statements was false because its allegations are based entirely on hindsight and the Third Circuit has "long rejected attempts to plead fraud by hindsight." *Chubb*, 394 F.3d at 158; *accord In re Rockefeller*, 311 F.3d at 225 (the PSLRA bars claims based on "fraud by hindsight").

When the FDA, in June 2017, finally asked Endo to withdraw reformulated Opana ER from the market, it did so expressly "based on a review of all available postmarketing data" at that time and "its concern that the benefits of the drug may *no longer* outweigh its risks" in the context of an "opioid epidemic" that required novel changes in the FDA's regulatory approach. (¶ 149 (emphasis added).) Indeed, the FDA expressly acknowledged that its request was the "first time" that it had requested withdrawal of such a medication "due to the public health consequences of abuse" rather than the risks of medication when used as instructed. (¶ 149; *see also* Ex. 3.) Plaintiff alleges *no facts* establishing that any defendant had reason to believe that the FDA would take this unprecedented step ahead of time. It is black-letter law that "[t]o be actionable, a statement or omission must have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002). Even in cases where Section 11 claims are not subject to heightened pleading standards (as this case is), a "[p]laintiff[] must, at a minimum, plead facts to demonstrate that allegedly omitted facts both existed, and were known or knowable*, at the time*

of the offering." *Castlerock Mgmt. Ltd. v. Ultralife Batteries, Inc.*, 114 F. Supp. 2d 316, 323 (D.N.J. 2000) (emphasis added).[11] Plaintiff has done none of this here.

The Amended Complaint tries to plead a misstatement by pointing to "post-marketing data" (¶ 203) and various "studies" (¶ 160) that supposedly contradict Defendants' statements. This effort fails.

a. The Post-Marketing Data Post-Date The Challenged Statements And Cannot Render Any Statement False

The Amended Complaint's clearest example of impermissible hindsight pleading is its reliance on "post-marketing data" to try to show false statements. (*See* ¶ 203 (citing ¶¶ 123-27, 130-31, 141-44).) But those NAVIPPRO, RADARS and FAERS charts expressly state that they were created *years later*, *in 2016 and 2017*. (*See* ¶ 123 ("Source: Figure generated by reviewer using data from NAVIPPRO[] Final Study Report, submitted by Endo Pharmaceuticals December 21, 2016."); ¶ 124 ("Source: NAVIPPRO[] Final Study Report, submitted by Endo Pharmaceuticals December 21, 2016"); ¶ 126 ("Source: updated response to June 1, 2016 FDA Information request, submitted by Endo Pharmaceuticals November 28, 2016"); ¶ 130 (chart reflecting information through 2016); ¶ 131 (chart alleged to include information "between December 2011 and June 2016"); ¶¶ 141-44 (purporting to describe FDA "briefing documents" published on "March 9, 2017").) Nothing in the allegations shows that this information was available to any defendant at the time they made the challenged statements.[12]

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[11] Plaintiff cites as a source of a disclosure duty Item 303 of SEC Regulation S-K. (¶¶ 222, 224, 372.) Item 303, like the securities laws generally, does not permit hindsight pleading. It requires, under certain circumstances, the disclosure of "known" trends and other factors. *See Garber v. Legg Mason*, 537 F. Supp. 2d 597, 611 (S.D.N.Y. 2008).

[12] The earliest any of these charts is dated in November 28, 2016. (¶ 126.) The handful of statements that post-date these charts are not factually alleged to be false. There is nothing suggesting that Endo did not "do[] a lot of work around OPANA's reformulation" to make abuse

Such blatant hindsight pleading cannot state a claim. *See Williams v. Globus Med., Inc.*, 869 F.3d 235, 244 (3d Cir. 2017) (dismissing claims as nothing more than "conjecture based on subsequent events"); *In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x 124, 131 (3d Cir. 2017) ("[N]o well-pled allegation supports the claim that the FDA reformulated its thinking prior to the advisory committee meeting."); *Winer Family Tr. v. Queen*, 503 F.3d 319, 332 (3d Cir. 2007) (affirming dismissal based on an "impermissible attempt to prove fraud by hindsight"); *In re CIT Grp., Inc. Sec. Litig.*, 349 F. Supp. 2d 685, 691-92 (S.D.N.Y. 2004) (dismissing Section 11 claim based on disclosure of $554.9 million credit loss three weeks after securities offering because plaintiff alleged no facts establishing that the loss was known at the time of the offering).

b. None Of The "Studies" Plaintiff Cites Establishes A False Statement

Plaintiff also does not establish a false statement based on the "studies" it cites. Where, as here, a plaintiff attempts to allege a false statement based on contrary documents or reports, the Third Circuit requires it to "identify who authored the alleged report, when it was authored, who reviewed the report, and what data its conclusions were based upon." *Chubb*, 394 F.3d at 147; *accord Clark v. Comcast Corp.*, 582 F. Supp. 2d 692, 705 (E.D. Pa. 2008) ("Reliance upon alleged documents which are undated, unquoted, undescribed, and unattached amounts to nonspecific allegations, at best.").

The Amended Complaint does not come close to meeting this standard. In an effort to support a misstatement using information that supposedly pre-dates the challenged statements,

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more difficult (¶ 246) or that it was not "designed to be crush-resistant" (¶ 252), even if eventually its crush resistance did not adequately preclude abuse. There are also no facts showing that Endo's 2017 disclosure concerning the FDA's Advisory Committee's vote was inaccurate. (¶¶ 254-63.) *See In re Amarin Corp. PLC Sec. Litig.*, No. 13-CV-6663 (FLW)(TJB), 2016 WL 1644623, at *12 (D.N.J. Apr. 26, 2016) (no misstatement where it was "not a mischaracterization of the FDA's position as of the date the statement was made"), *aff'd* 689 F. App'x 124.

paragraph 160 of the Amended Complaint cross-references "studies" in other paragraphs: "Study 108" (¶ 68), "Study 109" (¶ 69), "Study 901 and Study 902" (¶ 71). But the Amended Complaint provides virtually no *facts* about those studies. It vaguely describes Study 108 as an "*in vivo* bioavailability study" that "showed that reformulated Opana ER seemed to resist crushing forces from a pill crusher" but that other forms of tampering were "possible." (¶ 68.) It asserts that "Study 109" "was an *in vivo* human abuse potential and drug-liking study" to "evaluate the relative bioavailability and subjective effects" of reformulated Opana ER that "showed that chewing reformulated Opana ER tablets . . . produced positive subjective effects significantly higher than those produced by ingesting intact reformulated Opana ER." (¶ 69.) The descriptions of "Study 901" and "Study 902" are similarly opaque. (¶¶ 71-72.)[13]

This does not come close to what Third Circuit law requires. It does not identify the studies' authors, methodologies, data or and findings. Instead, Plaintiff offers its own general characterizations of the studies and asserts that defendants' statements were inconsistent with those general characterizations. This circular, "barebones sketch . . . utterly fails to meet" the pleading standards "in any respect." *Chubb*, 394 F.3d at 148; *accord Comcast Corp.*, 582 F. Supp. 2d at 705 (plaintiffs' reliance on "barebones" allegations regarding internal documents has "been foreclosed by *Chubb*"); *In re Adolor*, 616 F. Supp. 2d at 566 (no misstatement where "Plaintiffs do not support their definitions with citations to FDA guidelines or assert that the definitions are the industry standard").[14]

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[13] The Amended Complaint also refers to a "Study 113" and "Study 114," but does not appear to base any alleged misstatements on them. (*See* ¶¶ 160, 189, 203.)

[14] The Amended Complaint alleges that the statements in paragraphs 196 and 199 are misleading based on paragraph 189. (¶¶ 196, 199.) Paragraph 189, however, alleges no facts. It refers obliquely to "post-marketing data" and "data," but alleges none of the data, its sources, authors or anything about it. This, too, is woefully deficient under *Chubb.*

3. The Challenged Statements Are Inactionable As Opinions, "Puffery" And Forward-Looking Statements

In addition to the other bases for dismissal, nearly all of the statements plaintiffs challenge are inactionable because they are protected as opinions, general corporate optimism (or "puffery") and/or forward-looking statements covered by the PSLRA "safe harbor."

a. Defendants' Interpretations Of Data And Other Expressions of Opinion Are Inactionable

It is well-settled that expressions of opinion are not actionable unless they are both objectively false (*e.g.*, incorrect) and subjectively false (*e.g.*, the speaker did not believe them). *Pfizer, Inc.*, 754 F.3d at 170. A sincerely held opinion may be actionable under Section 11 if it omits material information in such a way as to render it misleading. *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1329 (2015).[15]

Many of the statements Plaintiff challenges are subjective opinions and interpretations of clinical and testing data. (*See*, *e.g.*, ¶¶ 157-59, 161, 168, 170, 172-74, 177, 179, 181-83, 185-87, 190, 195, 198, 200, 226-27, 232, 237, 246.) The Third Circuit has held that "[i]nterpretations of clinical trial data are considered opinions." *Pfizer, Inc*., 754 F.3d at 170 (citations omitted). Many other challenged statements are also opinions: they reflect that that the speakers were "optimis[tic] or "hopeful" that the FDA would permit an abuse-deterrent label. (¶¶ 226-27, 232; *see also* ¶¶ 163, 166, 168, 171, 177, 191, 204, 206, 219, 237, 241.) *See In re Bristol-Myers Squibb Sec. Litig.,* 312 F. Supp. 2d 549, 557-58 (S.D.N.Y. 2004) (a "reasonable investor" would understand statements to be opinions, not "guarantees," where statements included language such as "we think," "potential," and "hopefully").

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[15] The Third Circuit has declined to extend *Omnicare* to Exchange Act claims. *Amarin Corp.*, 689 F. App'x at 132 n.12.

None of these is actionable. Plaintiff alleges no facts establishing that any were objectively false (for the reasons described above), and no facts demonstrating that the speakers did not believe them (for the reasons described below). *Pfizer*, 754 F.3d at 170-71 (affirming dismissal of claims challenging on opinions concerning drug studies); *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 531(S.D.N.Y. 2015) (dismissing claims based on opinions that "the company expects the FDA to approve" a drug because no facts established "that defendants did not genuinely believe what they were saying at the time they said it"). A complete list of these statements is set forth in Exhibit 4.

b. Other Statements Are Inactionable "Puffery"

Numerous statements cited by Plaintiff are general expressions of corporate optimism, or "puffery," and are inactionable as a matter of law. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1420,1427 (3d Cir. 1997) ("Claims that these kinds of vague expressions of hope by corporate managers could dupe the market have been almost uniformly rejected by the courts.") Such statements are inactionable because they are "too general to cause a reasonable investor to rely upon them." *Bldg. Trades United Pension Tr. Fund v. Kenexa Corp.*, No. CIV.A. 09-2642, 2010 WL 3749459, at *11 (E.D. Pa. Sept. 27, 2010) (quotation omitted).

The Amended Complaint is replete with such optimistic characterizations. There are statements that data or studies were "very supportive," "very encouraging," "robust," "compelling," "going in the right direction," "sufficient," "[going] well," or "positive" (¶¶ 171-73, 226, 237), and that Endo was "optimis[tic]," "cautiously optimistic," was "making progress," or had "momentum" about labeling (¶¶ 210, 211, 232). Courts regularly recognize that optimism regarding an FDA application is too vague to form the basis for a securities claim. *See In re EDAP TMS S.A. Sec. Litig.*, No. 14 Civ. 6069 (LGS), 2015 WL 5326166, at *10 ("[I]nsofar as

. . . statements place a positive spin on developments in the [FDA] process, they constitute inactionable puffery and corporate optimism."); *Gillis*, 197 F. Supp. 3d at 597 (hopeful statements about FDA approval constituted immaterial puffery). The same result is warranted here. A complete list of the statements that are inactionable puffery is set forth in Exhibit 5.

c. Plaintiffs Challenge Forward-Looking Statements That Are Protected By The PSLRA "Safe Harbor"

Plaintiffs challenge many forward-looking statements. Under the PSLRA "safe harbor," it is black-letter law that forward-looking statements, including "plans and objectives" and "projection[s]," 15 U.S.C. § 78u-5(i)(1), are immunized from liability under certain circumstances. The circumstances are: if (i) the statement "is identified as such and accompanied by meaningful cautionary language," (ii) it "is immaterial," or (iii) "the plaintiff fails to show [that] the statement was made with actual knowledge of its falsehood." *Globus Med.*, 869 F.3d at 245 (quotation omitted); 15 U.S.C. § 78u-5(c). A forward-looking statement is protected by the safe harbor if any prong applies. *See id.* Statements about expected FDA approval "are classically forward-looking, as they address what defendants expected to occur in the future." *See Gillis*, 197 F. Supp. 3d at 585.

Forward-looking statements in the Amended Complaint include: Endo "expect[s]" data would support its Citizens Petition (¶ 171); Endo "will hopefully," "would hopefully," or "if all goes well, [Endo] will be able to file" with the FDA to support abuse-deterrent labeling (and similar phrases) (¶¶ 204, 206, 211, 232); Endo's labeling request "will potentially" lead to the addition of abuse-deterrent labeling (¶ 231); and Endo "anticipate[s]" additional data and "will seek collaboration" with the FDA (¶ 250). Plaintiff has not alleged "actual knowledge" as to the falsity of any of the above statements and they are therefore inactionable. *See Sanofi*, 87 F.

Supp. 3d at 529-30. Each is also accompanied by meaningful cautionary language, bringing them well within the protections of the PSLRA. (*See* Ex. 6.)

A complete list of the forward-looking statements plaintiffs challenge is set forth in Exhibit 6.

4. No Individual Defendant Made A False Statement

The U.S. Supreme Court has held that a defendant cannot be liable under Section 10(b) for statements that defendant did not make. *See Janus Capital Grp., Inc. v. First Deriv. Traders*, 564 U.S. 135, 138 (2011). Here, Plaintiff purports to bring Section 10(b) claims against nine Exchange Act Individual Defendants—*most of whom allegedly uttered only one statement* during the five-year class period. Plaintiff does not establish that any of their statements was false:

- Paul V. Campanelli: Plaintiff attributes to him *two* statements in May 2017 regarding interactions with the FDA (¶¶ 261, 262), but alleges no facts establishing that Endo was not "laser focused with the FDA" or did not "hope" to have a meeting with the FDA "shortly."

- Blaine T. Davis: Plaintiff attributes to him *one* statement in February 2013 regarding "two surveillance databases" showing a "significant reduction in abuse by those methods," presumably the methods by which old Opana ER were abused, (¶ 174), but alleges no facts establishing which "databases" or what "methods" were even discussed—much less that Mr. Davis's statement was incorrect.

- Matthew W. Davis: Plaintiff attributes to him *one* statement in March 2017 stating that "Endo remains confident that the body of evidence established through clinical research demonstrates that OPANA ER has a favorable risk-benefit profile when used as intended in appropriate patients" (¶ 255), but alleges no facts establishing that Endo was not "confident" or that there was not a "favorable risk-benefit profile" when used "as intended" (as opposed to abused).

- Ivan Gergel: Plaintiff attributes to him *four* statements in February 2013 regarding Endo's "confiden[ce] that the FDA will remove the non-abuse deterrent Oxymorphone products in May" and various interpretations of data on abuse rates (¶¶ 171-74), but alleges no facts establishing that Endo lacked such confidence or that the data interpretations were not appropriate.

- Susan Hall: Plaintiff attributes to her *one* statement in August 2016 stating that "We anticipate the generation of additional data and we will seek collaboration with [the]

FDA to appropriately advance OPANA ER" (¶ 250), but alleges no facts establishing that Endo did not anticipate doing just that or that it did not.

- David P. Holveck: Plaintiff attributes to him *one* statement in November 2012 that "[s]ufficient evidence exists to support the determination that the old formulation of OPANA ER was discontinued for reasons of safety" (¶ 158), but Plaintiff expressly concedes that it was not until May 2013—*six months later*—that the FDA informed Endo that it "could not reach the conclusion that original Opana ER was withdrawn for reasons of safety or effectiveness." (¶ 109.)

- Alan G. Levin: Plaintiff attributes to him *one* statement in March 2013 regarding "real world evidence" showing that the new formulations have a "meaningful impact in terms of abuser behavior" and that "the data seems to demonstrate that we have put a safer version of our formulation out at the market and that is all part of the dialog that we're having with the FDA now" (¶ 179), but alleges no facts establishing what "evidence" Plaintiff contends did not support his opinion or that Endo was not having a dialog with the FDA (which, of course, it was (¶¶ 99-106)).

- Julie H. McHugh: Plaintiff attributes to her *one* statement in February 2013 that "an additional quarter of surveillance data" showing lowered abuse rates compared to "generic" products (¶ 170), but no facts establishing that that quarter of data did not show such lowered abuse rates.

Plaintiff does not allege a single contemporaneous fact contradicting any of these individuals' statements. A Section 10(b) claim simply cannot be maintained against any of them. *See Solomon-Shrawder v. CardioNet, Inc.*, No. 09-3894, 2010 WL 3168366, at *12 (E.D. Pa. Aug. 10, 2010) (dismissing claims where plaintiff failed to plead facts showing that any defendant's statement was false). Plaintiff had no factual basis to name these individuals defendants in this case. It would be fundamentally unfair to force any of these individuals to remain in this case and to defend themselves against the serious charge of securities fraud. Every one of the Exchange Act Individual Defendants should be dismissed.[16]

[16] The only other individual Section 10(b) defendant is Rajiv De Silva, a former Endo CEO, to whom Plaintiff attributes 18 supposed misstatements. (¶¶ 197, 198, 200, 204, 206, 210, 211, 219, 225, 226, 227, 231, 232, 233, 237, 241, 242, 246.) Though too numerous to address individually, plaintiffs also fail to allege facts demonstrating that these statements are false and, in any case, all of the statements fail for the additional reasons discussed above.

D. Plaintiff Has Not Shown A "Strong Inference" Of Scienter

In order to plead a Section 10(b) claim, a plaintiff must "state with *particularity* facts giving rise to a *strong inference* that the defendant acted with the required state of mind," *i.e.*, with scienter. *See* 15 U.S.C. § 78u-4(b)(2) (emphases added). Scienter is an "intent to deceive, manipulate, or defraud" as to *each* defendant and *each* alleged misstatement. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007) (quotation omitted). The Third Circuit has held that "'motive and opportunity' may no longer serve as an independent route to scienter." *Gold v. Ford Motor Co.*, 577 F. App'x 120, 123 (3d Cir. 2014) (citation omitted). Instead, to establish scienter in the Third Circuit, a plaintiff must plead facts establishing a "strong inference" of "reckless or conscious behavior." *Id*. This is a stringent standard under which "omissions and ambiguities count against inferring scienter." *Tellabs*, 551 U.S. at 326. The U.S. Supreme Court has held that, to meet this exacting scienter pleading standard, a plaintiff must do more than allege "facts from which . . . a reasonable person *could* infer that the defendant acted with the required intent," for that "does not capture the stricter demand Congress sought to convey." *Id.* at 314. Instead, to be "strong," the inference of scienter must be "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference." *Id.* Plaintiff does not meet that standard.

1. Plaintiff Alleges No Conscious Misbehavior Or Recklessness

Not only is motive no longer an independent basis for scienter, but where (as here, for the reasons explained below), there is an absence of motive, allegations of recklessness or conscious misbehavior must be "correspondingly greater." *GSC Ptrs. CDO Fund v. Washington*, 368 F.3d 228, 238 (3d Cir. 2004) (citation omitted). "Recklessness or conscious misbehavior" in this

context requires "not merely simple, or even inexcusable negligence, but an 'extreme departure' from the standards of ordinary care" that "presents a danger of misleading [investors] that is either known to the defendant or is 'so obvious' that the defendant 'must have been aware of it.'" *In re Radian Sec. Litig.*, 612 F. Supp. 2d 594, 613 (E.D. Pa. 2009) (quoting *GSC Partners*, 368 F.3d at 239). Plaintiff does not come close to meeting this standard here as to any defendant.

As an initial matter, as explained above, Plaintiff has not pled facts establishing that *any* of the studies or post-marketing data concerning Opana ER contradicted any statement by any defendant at the time. This alone precludes an inference of scienter. *In re Nice Sys., Ltd. Sec. Litig.*, 135 F. Supp. 2d 551, 585 (D.N.J. 2001) ("[a] plaintiff cannot simply couple" allegations of false statements "with conclusory allegation[s] of fraudulent intent to adequately plead scienter") (quotation omitted) (brackets in original); *Sanofi*, 87 F. Supp. 3d. at 545 (no scienter where "the FDA's comments simply did not contradict Sanofi's public statements"). That the FDA convened an Advisory Committee in 2017 to assess the safety and abuse-deterrence of reformulated Opana ER (¶ 137), and that the committee, after studying all data available at that time, divided by a vote of 18 to 8 in finding that the benefits of Opana ER no longer outweighed the risks (¶ 146), shows that that "researchers may well differ over . . . the interpretation of test results." *Gillis*, 197 F. Supp. 3d at 604 n.36 (quotation omitted). This fully undermines any inference that there were facts so obvious about Opana ER's safety that any defendant did not believe their optimistic statements concerning the medication. *See In re Columbia Labs. Inc. Sec. Litig.*, 602 F. App'x 80, 84 (3d Cir. 2015) (noting that "the FDA's decision to convene an Advisory Panel" undermines an inference of scienter regarding adverse clinical trial results).

Moreover, as to the nine Exchange Act Individual Defendants, the Amended Complaint does not allege a single fact suggesting that *any* of them saw or recklessly ignored the studies or

post-marketing data that supposedly contradicted public statements.[17] This, too, precludes any inference of scienter. *See In re NutriSystem, Inc. Sec. Litig.*, 653 F. Supp. 2d at 578 (no scienter because "[t]he complaint never identifies which defendant knew this information . . ."); *City of Taylor Gen. Emps. Ret. Sys. v. Magna Int'l Inc.*, 967 F. Supp. 2d 771, 800-01 (S.D.N.Y. 2013) (no scienter where plaintiff failed to "identify any contemporaneous data or information that defendants either possessed and disregarded, or failed to consider"). *This is dispositive as to the individuals*. Plaintiff alleges that virtually all of the individual defendants made only *one* or a few statements, as shown above, yet Plaintiff does not even attempt to show that any of them knew or intentionally ignored *any* fact that rendered their statement false. This is a basic requirement of securities fraud claims and Plaintiff ignores it entirely. There can be no inference of scienter as to these individuals as a matter of law. *See Oran v. Stafford*, 226 F,3d 275, 290 (3d Cir. 2000) (affirming dismissal of individual defendants for failure to plead "particularized facts that give rise to a strong inference of fraudulent intent"); *Adolor*, 616 F. Supp. 2d at 575 (no scienter where "the Amended Complaint fails to allege facts demonstrating that Defendants had knowledge that would have made the[ir] statements false").[18]

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[17] Several defendants did not arrive at Endo until several years after these studies, and there is no basis to suggest that they uncovered the studies when they arrived. (*See* ¶ 27 (Mr. Campanelli became Endo's CEO in September 2016 and headed a division unrelated to these allegations beginning in 2015); ¶ 28 (Blaine Davis's employment began in January 2015); ¶ 29 (Matthew Davis's employment began in January 2017).) The NAVIPPRO, RADARS and FAERS data plaintiffs cite is from 2016 and 2017—well after virtually every statement at issue. Many of the individual defendants were not even employed at Endo at that time. (*See* ¶ 31 (Mr. Gergel left Endo in March 2014); ¶ 33 (Mr. Holveck retired in December 2012); ¶ 34 (Mr. Levin left Endo in "the fall of 2013"); ¶ 35 (Ms. McHugh left Endo in May 2013).) There is no scienter because there is no allegation "connect[ing]" *any* defendant "to the use of fraudulent practices." *In re Am. Bus. Fin. Servs., Inc. Sec. Litig.*, 413 F. Supp. 2d 378, 403 (E.D. Pa. 2005).

[18] Plaintiff makes a number of allegations concerning Endo's litigation with Impax, another pharmaceutical company. (¶¶ 64-65.) These are *non sequiturs*. To the extent that Plaintiff intends these allegations to support an inference of scienter, they do not. They have no

2. Plaintiff Alleges No Motive To Engage In Fraud

Plaintiff makes no effort to identify a specific motive as to why any defendant would engage in securities fraud. No stock sales or other profit-taking are alleged by any defendant. The absence of such sales undermines any inference of scienter. *See In re PDI Sec. Litig.*, 02-Civ-0211 (GEB), 2006 WL 3350461, at *16 (D.N.J. Nov. 16, 2016) ("the fact that Defendants did not sell a single share of their own stock during the Class Period effaces Plaintiffs' assertions about Defendants' motives."). To the extent that Plaintiff suggests a motive to sell Opana ER, this is precisely the type of "generic corporate motive" that is legally insufficient to establish scienter. *In re Amarin Corp. PLC*, 13-CV-6663 (FLW)(TJB), 2015 WL 3954190, at *11 (D.N.J. June 29, 2015) (finding insufficient allegations of motive "to continue [the company's] success"); *Nice Sys.*, 135 F. Supp. 2d at 584 ("the allegation that Defendants made false and misleading statements to secure market share is similarly insufficient to demonstrate Defendants had a motive to commit fraud").

3. The More Compelling Inference Under *Tellabs* Is Non-Fraudulent

That Plaintiff, with 20/20 hindsight after the FDA's adverse decision in 2017—more than five years after the FDA found reformulated Opana ER "safe and effective" (¶ 78)—now disagrees with defendants' positive views about reformulated Opana ER does not establish scienter. The far more compelling inference, which the Court is required to consider under *Tellabs*, is that Endo and its executives advocated for Opana ER with the FDA over five years, were optimistic that they would succeed, and that, in a changing environment with additional data and a new focus on opioid abuse (¶¶ 47-49), the FDA eventually reached a different

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connection to any alleged misstatement and are therefore irrelevant. *Columbia Labs.*, 2013 WL 5719500, at *5 (no scienter where "[p]laintiffs provide[d] no connection between the . . . allegations and the allegedly misleading statements"), *aff'd*, 602 F. App'x 80 (3d Cir. 2015).

conclusion. (¶¶ 146, 149.) That simply is not securities fraud. *See*, *e.g.*, *Columbia Labs.,* 2013 WL 5719500, at *7 (dismissing case where non-fraudulent intent was a more compelling inference than scienter based on failed efforts to obtain FDA approval); *Sanofi*, 87 F. Supp. 3d at 544 (dismissing case where "the most logical inference" is that defendants "sincerely held their optimistic views" and "were surprised and disappointed by" the FDA's adverse decision).[19]

III. PLAINTIFF'S "CONTROL PERSON" CLAIMS UNDER SECTION 20(A) OF THE EXCHANGE ACT AND SECTION 15 OF THE SECURITIES ACT SHOULD BE DISMISSED FOR FAILURE TO ESTABLISH A PREDICATE VIOLATION

Plaintiff asserts "control person" claims, under Section 20(a) of the Exchange Act and Section 15 of the Securities Act. To state a Section 20(a) claim, Plaintiff must plead a predicate Section 10(b) claim. *Pfizer*, 754 F.3d at 177. To state a Section 15 claim, it must plead a predicate Section 11 claim. *See Klein v. Gen. Nutrition Co.*, 186 F.3d 338, 344 (3d Cir. 1999) ("[C]ontrolling person liability under section 15 . . . hinges on liability under . . . [Section 11.]"). Because Plaintiff's Section 10(b) and Section 11 claims fail as a matter of law, their Section 20(a) and Section 15 claims must also be dismissed. *See Pfizer*, 754 F. 3d at 177 (affirming dismissal of Section 20(a) claims where Section 10(b) claims were dismissed); *Klein*, 186 F.3d at 344 (affirming dismissal of Section 15 claims where Section 11 claims were dismissed).

Conclusion

The Amended Complaint fails to state a claim as a matter of law as to any defendant. It should be dismissed not only as to Endo and Endo Health Solutions Inc., but also as to every

[19] Plaintiff's attempt to allege scienter on the theory that reformulated Opana ER was called Endo's "primary product" (¶ 308) also fails. It is long-standing law in this circuit that courts may not find a strong inference of scienter because the statements in question pertained to the company's core product or business, in the absence of particularized allegations "showing that defendants had ample reason to know of the falsity of their statements." *In re Stonepath Grp., Inc. Sec. Litig.*, No. Civ.A. 04-4515, 2006 WL 890767, at *12 (E.D. Pa. Apr. 3, 2006).

individual defendant. Plaintiff lacks any factual basis to maintain a claim against the individual defendants.

Respectfully submitted,

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